

### **REMARKS**

Claims 1-9, 11-20, 24-26, 28, 30, 32-40, 67-72, 75-76, 77-82 and 87-90 stand rejected under 35 USC 102(b) on the basis of Engelman.

Claims 1-10 stand rejected under 35 USC 102 (b) on the basis of Mercer et al.

Claims 27 and 29 stand rejected under 35 USC 103(a) on the basis of Engelman.

Claim 32 stand rejected under 35 USC 103(a) on the basis of Engelman in view of Swartz.

Claims 73-74 stand rejected under 35 USC 103(a) on the basis of Engelman in view of Suzuki.

Claims 21-23 and 31 were indicated to be allowable if rewritten in independent form including all of the limitations of any intervening claims. These claims have been amended in accordance with the Examiner's suggestion and have been rewritten in independent form to include the limitations of the intervening claims and are therefore believed to be allowable.

Although Applicants believed that the claims previously submitted defined patentably over the references, many of the claims have been further amended to more clearly define patentably over the references and to overcome the 102 and 103 rejections.

Before examining the claims in detail, the invention and the main references will be briefly reviewed to show that the cited references do not anticipate the claimed invention.

**A. For purpose of illustration, the Examiner's attention is directed to Figs. 1A through 1E of the application and the detailed description at pages 9 and 10 of the specification which illustrate the problem addressed by Applicants and resolved by the invention.** When the back of the heel rests on a relatively firm support surface, 16, of a bed 18, the weight onto and from point 11 is distributed along a relatively narrow cone-like portion of the soft tissue underlying point 11 (hatched region in Figs. 1B, 1C, 1D). Heel point 11 is not a sharp point but a rather small region and the weight at point 11 would extend over a small arc illustrated as going from 101 to 103 and be applied through the **portion of the soft tissue layer (shown as a hatched region) to outer skin layer 12.** **Soft tissue or soft tissue layers, as used herein and in the claims, refers to a composite material comprising multiple layers of skin, fat and muscle tissue located between the skeletal system [bone(s)] and the outer surface of the body (skin, or outer skin).** **The outer skin layer of the heel region makes contact with the underlying support surface 16 at a contact surface 21 defining a relatively small circular or elliptical area.** For ease of illustration, it is assumed that the weight is distributed across the soft tissue layers extending from point 11 to contact surface 21. As shown in Figs. 1B, 1C, 1D and 1E, at contact surface 21, the overlying body weight would be distributed over a region extending from 201 to 203.

Applicants recognized that the pressure exerted at any point below the heel point is a function of the weight (W) divided by the area (A) over which the weight is distributed. Applicants further recognized that, in many instances, the pressure is greatest at the interface between the bony point 11 and the soft tissue layer immediately below the bony point because much of the weight is concentrated at the bony prominence and the area over which the weight (W) is distributed is least at that point. **In effect, this makes the interface between the bone and the soft tissue (i.e., the area at, or just below, heel point 11, in Figs. 1A, 1B, 1C, 1D) the most susceptible to ulceration, at least for this example.**

**B. The Invention:** Applicants' invention may be illustrated with reference to Fig. 2A which is a simplified cross sectional view of a **prosthesis 20 shaped to conform to, or to be conformable with, the outer shape of the foot with which they are in contact.** Ensuring conformance and good contact between the inner surfaces of the prosthesis and the outer skin layer results in better weight distribution and a larger decrease in the pressure at the bony prominence-soft tissue interface (11) and across the soft tissue layer between regions 11 and 21.

The role of the prosthesis in reducing the pressure at the interface between the heel point 11 and the underlying soft tissue, and across the soft tissue layer between point 11 and the entire outer surface surrounding point 21 may be further illustrated by reference to Figs. 2A, 2B, 3A, 3B and 3C. **In Fig. 3A, lines representing the weight exerted at region 11 are drawn radiating out of point/region 11 with arrow heads pointing away from point 11 and towards surface 16.** These lines radiate out across the soft tissue layer below point 11 and across the prosthesis sections 17a, 17b and 17c terminating along the support surface 16. **The radiating lines are intended to illustrate how the weight present at point 11 is distributed over an ever increasing area and volume through the soft tissue layer and the prosthesis 17.** In a like manner, Fig. 2B illustrates that, with the prosthesis present, the region 11 along which the body part weight is distributed extends from a point 111 to a point 113 along the interface between bony prominence 11 and the underlying soft tissue layer. The length of this arc-like distance is much greater than the length of the arc

ranging from 101 to 103 (see Fig. 1B and cross hatched portion of Fig.2B) when a prosthesis is not present.

In accordance with the invention, a prosthesis is applied between the bony prominence and the body part containing the bony prominence and a support surface or structure as shown, for example, in Figs. 2A and 2B (as well as Figs. 3A, 3B and 3C, among others) which ensures that the weight (W) at the bony prominence is distributed over a larger area to reduce the pressure at all the interfaces. Thus, by comparing the prior art (e.g., Figs. 1C and 1D) with the invention (e.g., Figs. 2A, 2B, 3A, 3B and 3C), **it is obvious that in accordance with the invention the weight W is distributed over a much larger area. This aspect of the invention is not shown, taught or suggested in the cited references.**

Engelman shows two pads mounted on a board, within a block, to support or raise a leg. Engelman does not discuss surrounding the heel (or any bony prominence) with pressure reducing protective material in intimate contact with the heel over its entire weight-bearing surface. In contrast, Applicants' invention is directed to surrounding and/or subtending the bony prominence (of a body part) with a protective device in order to increase the area over which the weight at the bony prominence interface with the underlying soft tissue is distributed. This an integral part of Applicants' teachings and claims. **Engelman does not even suggest conforming a prosthesis around the heel (or the bony prominence of any other body part) to provide the distribution of the force**

**over an extended area and volume to reduce pressure at the bony prominence/soft tissue interface.**

Mercer et al relates to a cast formed around a body part and all the load of the body part is transferred to the cast material. **There is no teaching of distributing the load over an extended area and volume and to the use of a protective device which has an inner surface which conforms to the body part to be protected and which has an outer surface which conforms to the support surface.**

The Swartz et al reference is directed to a material which is sufficiently malleable to conform to a molding impression provided by a body part. There is no teaching or suggestion of forming a protective device to decrease pressure. The teachings of Swartz et al taken alone or in combination with the other references do not suggest Applicants' invention as claimed.

Suzuki (US 6,531,643) relates to an absorbent article which does not, by itself and/or in combination with any of the other references, show, teach or suggest the claimed prostheses or pads to relieve pressure at the interface between a bony prominence and its corresponding soft tissue layer to avoid or cure ulcers.

As already stated the claims have been amended to more clearly define over the references.

1- Claim 1, as amended, now calls for a body part to be protected which includes a bony prominence tending to concentrate the weight of the body part over a small region (A1) at the interface between the bony prominence and its

underlying soft tissue layer. Although such a body part exists in both Mercer et al and Engelman, neither of these references is directed to the issue of preventing the development of an ulcer at the interface between a bony prominence and its underlying soft tissue layer. That is, the problem faced and resolved by Applicants is **not** a problem addressed by Engelman and/or Mercer et al.

2- Claim 1, as amended, calls for a pad to be applied to the body part to be shaped so as to subtend and/or enclose the bony prominence. This is **not** shown or suggested in Engelman, who is concerned with **elevating a leg** and **immobilizing** it.

3- Claim 1, as amended, calls for the pad to include an inner surface conforming to the body part containing the **bony prominence**. A pad subtending and/or enclosing the bony prominence and conforming to the body part is **not** shown or suggested in Engelman. There is no teaching to reduce the pressure at the bony prominence/soft tissue interface.

4- Claim 1, as amended, calls for the pad to have an outer surface suitable for making contact with a support structure for increasing the area over which the weight is distributed. This is **not** shown or suggested in Mercer et al. This is also not suggested in Engelman where pads 14 and 17 (which are not in any way similar to Applicants' claimed pad) are placed in a block 10. In fact, these references teach away from this claim, since they show and teach confined structures to hold the body part, and do not relate to the bony prominence and to the distribution of the weight at the bony prominence.

5- Claim 1, as amended, calls for the pad to have a certain thickness and softness selected to be a function of the shape, size and weight of the bony prominence and body part to be protected. There is **no** showing or suggestion in Mercer et al and/or in Engelman for a pad to have a softness and thickness which is a function of the shape, size and weight of the bony prominence. This is an important feature of the invention and relates to the mechanism for reducing pressure at the bony prominence/soft tissue interface.

6 - Claim 1, as amended, calls for the pad to be shaped so as to extend **continuously from the area subtending (i.e., extending under) the bony prominence** to the support structure. Again, this is **not** shown, taught or suggested in Mercer et al and/or in Engelman.

7- Claim 1, as amended, also calls for the surface area and volume (which includes thickness) of the pad to be such that the pressure at the interface between the bony prominence and its surrounding soft tissue layer is less than the pressure causing a pressure ulcer to develop. Controlling the surface areas and the thickness and the softness of the pad such that the pressure at the interface between the bony prominence and its corresponding soft tissue layer is less than the pressure which would cause an ulcer is not shown, taught or suggested in Mercer et al and/or in Engelman and or in the combination of these references with the other references of record.

In summary, claim 1, as amended, calls for the pad to have the following features:

- a- an inner surface subtending the bony prominence and conforming to the body part containing the bony prominence;
- b- an outer surface suitable for making contact with the support structure for increasing the area over which the weight at the bony prominence is distributed;
- c- the inner and outer surface areas of the pad as well as the thickness of the pad and the softness of the pad material being selected to be a function of the shape, size and weight of the bony prominence and body part to be protected so as to distribute the weight of the body part over an extended area and over an extended volume to reduce the pressure present at the interface between the bony prominence and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure;
- d- the pad being shaped to enclose the portion of the body part containing the bony prominence and also the bony prominence;
- e- the pad being shaped to extend **continuously** between the area subtending the bony prominence and the support structure to increase the effective surface area and volume over which the concentrated weight at the bony prominence is distributed in the space between the bony prominence and the support



surface in order to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer to a level which is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

Claim 2, as amended, calls for the top surface of the pad to be sculpted (e.g. have a cut-out), as shown in Fig. 6A, 6B and 6C, so as to conform to the shape of the body part to be protected and for enabling the body part to be positioned within the sculpted region. This is not shown in the references and the allowance of claim 2, as amended, is respectfully requested.

Claim 3, as amended, emphasizes that the pad material may be an elastic material, or compliant mushy foam or a mesh material. Claim 3, as amended, also calls for the bottom surface of the pad to conform generally to the surface of the support structure. This is not suggested in Engelman and/or in Mercer. Accordingly, claim 3 is submitted to be patentable for its own reasons as well as those adduced for claim 1, from which it depends.

Claim 4, as amended, calls for the pad material to be of the type which (a) enables the top surface to conform to, and surround, the body part containing the bony prominence; and (b) the bottom surface to conform generally to the support surface for enabling the body part when positioned within the pad to distribute the weight concentrated at the bony prominence over a larger area than A1 at the interface between the bony prominence and the soft tissue layer and over an area which increases as the distance from the bony prominence to the support surface increases. This is illustrated, for example, in Fig. 3A and defines

patentably over the references of record. Note that, in contrast to the prior art, the pad material conforms to (or hugs) the body part thus providing desired weight distribution. This is not shown or suggested in the references.

Claim 5, as amended, recites that the pad may be selectively increased to decrease the pressure at the interface between the bony prominence and the corresponding soft tissue layer; and that the body part to which the pad is applied can be freely moved in any direction. This is not shown or suggested in the references.

Claim 6, as amended, calls for the thickness of the pad to be at least one quarter ( $1/4$ ) of an inch, and for the length of the pad to range from one quarter ( $1/4$ ) of an inch to more than six inches and the width of the pad to range from one quarter ( $1/4$ ) of an inch to more than six inches.

Claim 7 defines some of the body parts to be protected calls for the pad to conform to the shape of the body part containing the bony prominence of its respective body part and its outer surface is conformable to the support surface. This is not shown or suggested in the references.

Claims 8, 9, and 10 are cancelled without prejudice.

Claim 11, amended to depend from claim 1, calls for the pad to be made of a soft material whose outer surface is conformable to varied support structures and having sufficient thickness of at least one quarter ( $1/4$ ) of an inch to reduce the pressures developed within the body part to enable the body part to which the pad is applied to rest on the support structure for an extended period of time without developing a pressure ulcer between the bony prominence and the

corresponding soft tissue layer of the body part. This claim is submitted to define patentably over the cited references.

Claim 12 depends from claim 11 and calls for the outer surface of the pad making contact with the support structure to conform generally to the shape of the support structure.

Claim 13 dependent from claim 4 calls for the inner surface of the pad to conform to the shape of a heel and to extend from the arch to the ankle region, and for the portion of the outer surface of the pad making contact with the support structure to conform generally to the shape of the support structure.

Claim 14 depends from claim 13 and is submitted to be allowable for at least the same reasons as claim 14.

Claim 15 amended to depend from claim 1 calls for a pad extending beneath the foot and the heel and the full width of the foot and to be generally of cylindrical shape. This is not shown or suggested in the references.

Claim 16 amended to depend from claim 1 calls for a pad shaped like a semi-cylindrical sleeve located behind the ankle and leg and extending from below the foot to above the ankle.

Claim 17, amended to depend from claim 1, calls for the inner portion of the pad to extend around the bottom portion of the foot and ankle region and to have either a rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and/or a combination thereof.

Claim 18 calls for a pad to include means for securing the pad to its corresponding body part.

Claim 19 calls for the pad to be is placed around its corresponding body part so as to protect the body part regardless of the orientation of the body part on, or off, the support structure.

Claim 20 calls for the pad to be shaped so as to redistribute weight from the area of the bony prominence to other portions of the body part.

Claims 21, 22 and 23 indicated to be allowable if rewritten in independent form, have been so rewritten and are assumed to be in condition for allowance.

Claim 24 has been amended to emphasize that the protective device has: (a) a top, inner, surface conforming to the body part to which it is applied; (b) a bottom, outer, surface suitable for making contact with the support surface and generally conformable to the shape of the support surface for transferring the force due to the concentrated weight of the body part over a wider area than the small region; (c) a thickness of a least one quarter of an inch extending continuously from the region of the body part containing the bony portion to the support surface; and (d) a shape which is a function of the shape, size and weight of the body part and the bony portion for increasing the effective area over which the concentrated weight present at the interface between the bony portion and its surrounding soft tissue layer is distributed. This protective device reduces the pressure due to the bony point exerted at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in

contact with the support surface. This is not shown or suggested in the references.

Claim 25, dependent from claim 24, is similar to claim 2 in calling for the top surface of the pad to be sculpted to conform to the shape of the body part to be protected, and is submitted to be allowable for at least the same reasons as claims 1, 2 and 24.

Claim 26, dependent from claim 24, calls for; (a) the material of the prosthesis to be such that the inner surface of the prosthesis conforms to, and surrounds, the body part containing the bony prominence for enabling the body part to be positioned within the protective device and its weight to be distributed over a grater area; and (b) the protective device to be placed around the body part to protect the body part regardless of the orientation of the body part on the support surface.

Claim 27, dependent from claim 24, is submitted to be patentable for at least the same reasons as claims 1, 3, and 24.

Claims 28, 29, and 30 are submitted to be patentable for at least the same reasons as claims 1 and 24.

Claim 31, indicated to be allowable if rewritten in independent form, has been so rewritten and is assumed to be in condition for allowance.

Claims 32, 33, and 34 are submitted to be allowable for their own reasons as well as those advanced for claim 24, from which they depend.

Independent claim 35, as amended, is submitted to be patentable for at least the same reasons as claims 1 and 24.

Claim 36, dependent form claim 35, recites that the critical pressure causing a pressure ulcer is a function of the length of time a given pressure is present, and wherein selected properties of the protective structure applied to the body part, including its size, softness and thickness, are selected to have different values as a function of the length of time the body part is to be on the support surface. The selection of certain properties which have different values as function of time is not shown or suggested in the references.

Claim 37 is cancelled without prejudice.

Claim 38, dependent form claim 35, calls for the selection of properties for the protective device which change gradually as a function of time to gradually increase the area and volume over which the concentrated weight is distributed in order to gradually reduce the pressure at the interface between the bony portion and the soft tissue layer and the associated body part. This subject matter is not taught or suggested in the references and claim 38 is submitted to define patentably over the references.

Claim 39, dependent form claim 35, calls for selective characteristics of the protective structure to undergo change as a function of time for increasing the effective surface area and decreasing the pressure applied to the body part components. This subject matter is not taught or suggested in the references and claim 39 is submitted to define patentably over the references.

Claim 40 calls for a pad to be applied between the body part to be protected and the support surface to have : (a) an inner surface which conforms to the body part due to the inner surface having either a cut out or being of a

material which conforms to the body part; and (b) having an outer surface generally conformable to the shape of the support structure for effectuating the transfer of the weight of the body part over a larger area in order to reduce the pressure within the body part. Claim 40 also calls for the pad to surround the region of the body part containing the bony prominence to cause the effective area between the bony prominence and its underlying soft tissue layer to be equal to an area (A2) which is greater than the area (A1) without the pad., whereby the resulting pressure between the bony prominence and its underlying soft tissue layer is P2 which is equal to  $W/A2$ , where P2 is less P1; and the protective device is selected to make P2 have a value below a critical value which would tend to cause ulcers in the body part. This is not shown or suggested in the references and claim 40 is submitted to be patentable over the cited references.

**Claims 41 – 66 have been withdrawn from consideration.**

Claim 67 calls for a bone to soft tissue interface pressure reducing structure **implanted** at the site of the bony prominence, which pressure reducing structure functions to increase the contact area between the bony prominence and the surrounding soft tissue and thereby causes the weight due to the body part and the bony prominence to be distributed over a larger contact area with the soft tissue and to thereby decrease the pressure to which the soft tissue is exposed. The implanting of a bone to soft tissue interface pressure reducing structure shown, for example, in Figs. 22A-22D and Figs.21A-21D, is not shown, taught or suggested in any of the cited

references. It is believed that the Examiner previously overlooked the significance of the **implant**. Accordingly, claim 67 is submitted to be patentable over the cited references. .

Claim 68, dependent from claim 67, calls for the bone to soft tissue interface pressure reducing structure to be **a pad inserted between the bony prominence and its surrounding soft tissue layer** and to be fabricated from a material of similar or greater firmness to that of the bony prominence and which behaves in a similar manner to the bony prominence.

Claim 69, dependent from claim 67, calls for the bone to soft tissue **interface pressure reducing structure to be fabricated from a material of similar or less firmness to that of the soft tissue** and which behaves in a similar manner to the soft tissue layer in diffusing the weight between the bony prominence and the actual soft tissue layer.

Claim 70, dependent from claim 67, calls for the bone to soft tissue interface pressure reducing structure to be a pad fabricated from a material having a firmness varying from that of the bony prominence to that of the soft tissue and to a firmness softer than that of soft tissue.

Claim 71, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad fabricated from a material enabling the growth of at least one of new bone, new cartilage and new soft tissue in the region between the original bony prominence and the original soft tissue layer.



Claim 72, dependent from claim 70, recites that the pad material includes substances which serve as a matrix and seeding structure for the formation of new bone or new soft tissue or any suitable new matter.

Claim 73, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad formed of a fatty like substance which exhibits little, if any, dimensional change as a function of time.

Claim 74, dependent from claim 73, recites that the fatty substance may be one of silicone and wax which exhibit little dimensional change as a function of time.

Claim 75, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad formed of material having a first volume when first implanted and which expands to a predetermined size after implantation.

Claim 76, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is made of a material which dissolves over time.

It is submitted that claim 67 and claims 68 to 76 dependent directly or indirectly from are clearly patentable over the references and their allowance is respectfully requested.

Claim 77 calls for **a hard shell-like structure** protective device **of limited size** to be applied to a body part requiring protection. The claimed structures are shown, for example, in Figs. 14A-14F for the heel, Figs. 15A-15C for the hip; Figs. 16A-16D for the ischium; Figs. 17A-17B for the coccyx; Figs. 18A-

18B for the scapula; Fig. 19 for the occiput, and Fig. 20 for the elbow. This is not shown in the cited references and claim 77 is believe to be patentable over the references.

Claim 78 is cancelled without prejudice.

Claim 79, dependent from claim 77, names various of the body parts to be protected and that the inner surface of the shell-like structure conforms to its respective body part.

Claim 80, dependent from claim 79, recites that the inner surface of the shell-like structure includes a soft inner liner.

Claim 81, dependent from claim 79, recites that the outer surface of the shell like structure is covered with a soft material to prevent damaging or pressuring any other body parts.

Claim 82, dependent from claim 79, recites that the hard shell like structure is shaped to contour the body part to be protected and reduce pressure on the body part without immobilizing the body part.

**Independent claim 77 and claims 79-82 are submitted to be patentable and to define patentably over the references.**

Claims 83-86 are withdrawn.

Claim 87 calls for a **protective device for a bone structure which has undergone amputation, as** shown, for example, in Figs. 23A-23E and figs. 24A-24G. The protective device includes a pad applied to the body part to be protected having an inner surface conforming to the body part to which it is

applied and having an outer surface suitable for making contact with the support surface and generally conformable to the shape of the support surface.

Claim 88 recites that the body part to be protected is one that has been amputated, and wherein the support structure is a prosthesis, and wherein the pad is placed between the amputated portion of the body part and the prosthesis. This is not shown or suggested in any of the references.

Claim 89, dependent from claim 88, recites that the pad is formed of a soft material.

Claim 90, dependent from claim 88, recites that the pad is formed of a hard material.

Accordingly, claims 87-90 directed to the protection of a limb which has undergone amputation are believed to be patentable over the cited references.

Respectfully submitted

A handwritten signature in black ink, appearing to read "H. I. Schanzer", with a long horizontal flourish extending to the right.

Henry I. Schanzer

Reg. No. 25,219